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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,151

01/27/2005

Tomas Carlsson

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EXAMINER

BADR, HAMID R

ART UNIT

PAPER NUMBER

1794

NOTIFICATION DATE

DELIVERY MODE

04/30/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,151	<b>Applicant(s)</b> CARLSSON, TOMAS	
	<b>Examiner</b> HAMID R. BADR	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 12-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/27/2005, 9/10/2007</u> .                                    | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's election without traverse of Group I (Claims 1-11) in the reply filed on 01/26/2009 is acknowledged. Claim 12-41 are withdrawn for further consideration.
2. Claims 1-11 are being considered on the merits.

### ***Objection to Claims***

Claim 1 is objected to for the word "hydrolysatation" in step f. It is suggested to use [hydrolysis] instead. Correction is required.

Claims 5 and 11 are objected to for "hydroxy apatite". This compound is written in one word as [hydroxyapatite]. Correction is required.

### ***Use Claims***

3. Claims 7-11 provide for the use of the method, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 7-11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 is indefinite for “b. in the range of 40-62C, preferably 45-58C” . A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 (step b) recites the broad recitation 40-62C, and the claim also recites 45-58C which is the narrower statement of the range/limitation.

7. Claim 1 is indefinite for "step d. pH of the water is adjusted by adding calcium".

Since the chemical form of calcium is not claimed and elemental calcium cannot be used to adjust pH, it is not clear what is meant by "calcium". It is unclear what the applicant regards as the invention.

8. Claim 1 is indefinite for "step g. heating the hydrolysate to 75-100C, preferably 85-95C". claim 1 (step g) recites the broad recitation 75-100C, and the claim also recites 85-95C which is the narrower statement of the range/limitation.

9. Claim 1 is indefinite for "step f. adding a pH adjuster to maintain the desired pH value of the hydrolysate". Since acids or bases can be used to adjust the pH of the medium, but not necessarily to maintain the pH at a desired level, using [buffer] instead of "pH adjuster" is suggested. It is unclear what is meant by "pH adjuster to maintain the desired pH".

10. Claim 1 is indefinite for "step f. desired pH value". It is not clear what is meant by "desired". It is unclear what the applicant regards as the invention.

11. Claim 2 is indefinite for "10-40%" preferably "20-30%". claim 2 recites the broad recitation 10-40%, and the claim also recites 20-30% which is the narrower statement of the range/limitation.

12. Claim 4 is indefinite for "pH adjuster in step f is nitrogen gas, calcium". It is unclear how nitrogen gas is used to adjust pH or how elemental calcium can be used to adjust pH. Chemical forms of nitrogen and calcium should be indicated.

13. Claim 6 is indefinite for "salt content". It is not clear what is meant by "salt". If the salt is meant to be sodium chloride, the claim should clearly indicate that.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 5,053,234; here in after R1).

16. R1 discloses a method for producing protein hydrolysate. The method comprises using abattoir remains, fillet frames, trash fish, animal by products, usable entrails, and the like as raw materials (Col. 5, lines 54-57), grinding the raw materials using a grinder (Col. 6, lines 35-40), heating the ground raw material (Col. 6, lines 59-63), hydrolyzing the proteins in the ground material using either endogenous or extraneous proteolytic enzymes. (Col. 7, lines 3-20), adding water to the ground material (Col. 7, lines 34-40), adjusting the pH within the range 6.0-6.5 (Col. 7, lines 49-50), controlling the hydrolysis temperature at 60-65C, (Col. 7, lines 54-65), heat deactivating the enzymes at 79-93C, causing the rendering of fatty materials in addition to deactivation of enzymes (Col. 10, lines 29-40), screening the digested material to remove large particles (Col. 10, lines 44-52), screening of undigested material and re-circulating the undigested material to the digestion stage (Col. Lines 42-45), separating the oil by centrifugation of the mixture (Col. 15, lines 1-5, and 24-25), and concentrating the hydrolyzed protein (Col. 12, lines 14-20). The produce protein hydrolysate can be used as animal feed. (Col. 17, lines 28-34).

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17. Given that the heating stage involves the denaturation and coagulation of proteins, it is obvious that coagulated material can be separated using proper means known in the art.

18. Given that the water content of the ground raw material will affect the handling, and flow properties as well as the dispersion of enzymes in the ground material, it would be obvious to adjust the water content to levels as presently claimed.

19. It is also obvious to carry out the process batch wise as presently claimed. Using acids and bases to adjust the pH is also within the skill of the artisan.

20. Given that any rendered fatty material can be separate from the digested material as disclosed by R1, the fat content of the hydrolysate can be adjusted to predetermined levels including the presently claimed fat content.

21. Given that the protein hydrolysate can be prepared with various standards of quality, production of pharmaceutical grade, food grade, biotechnological grade and feed grade protein hydrolysate is also obvious to those of skill in the art. Various grades of protein hydrolysates are also known in the art.

22. Since all aspects of the production of protein hydrolysates are disclosed by R1, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to follow and modify the teachings of R1. One would do so to prepare protein hydrolysates having various quality standards for various purposes. Absent any evidence to contrary and based on the teachings of the cited reference, there would be a reasonable expectation of success in preparing protein hydrolysates.

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23. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 5,053,234; here in after R1), further in view of JP-2-97409 (hereinafter R2).

24. The disclosure by R1 is hereby incorporated by reference as outlined above.

25. While R1 is silent regarding the production of hydroxyapatite, when the raw material contains bones, a large quantity of the undigested material remaining after the hydrolysis will comprise bones. The bones remaining after the digestion stage, can be used for the production of hydroxyapatite.

26. R2 discloses a method for producing natural hydroxyapatite out of fish bones. (Abstract).

27. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to follow the teachings of R1 to produce protein hydrolysates and convert the remaining bones after the hydrolysis; following the method as disclosed by R2. One would do so to prepare a value added product form waste material. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in converting bones to hydroxyapatite.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr  
Examiner  
Art Unit 1794

/KEITH D. HENDRICKS/

Supervisory Patent Examiner, Art Unit 1794